510(k) SUMMARY

Title: DC 7

Submitter: DC International, LLC
David Boëgler
317-730-4601
DC International, LLC
624 Cypress Green Cir.
Wellington, FL 33414

NOV 0 7 2013

Contact: David Boëgler
317-730-4601
DC International, LLC
624 Cypress Green Cir.
Wellington, FL 33414

Date Prepared: June 2, 2013

Device Trade Name: DC 7

Common Name: Diode Laser Therapy System

Classification Name: Instrument, surgical, powered laser
GEX 21 CFR 878.4810

Predicate Devices: China Daheng Group Inc DenLase (K102669), Biolase Technology Inc
Diolase (K121327)

Device Description:

The DC International, LLC DC 7 is a medical grade, solid-state, infrared diode lasers (AlGaAs). The lasers are designed to deliver continuous or pulsed laser energy with a wavelength at 980 nm. The touch screen display consists of a user interactive screens that allows selection of continuous, pulsed and the, repetition rates, aiming beam on/off, procedural information display keys, a Standby/Ready key, the manual emergency stop button and the master key switch.

THE LASER SYSTEM: The laser system consists of a laser diode optical deck, cooling system, voltage power supply and system control electronics that include the touch screen control panel.

THE MAIN CONSOLE: Contains the major electrical components

DELIVERY SYSTEM: The DC 7 is delivered with fibers, handpieces and tips Safety glasses/goggles and a safety sign are also provided with the systems.

	DC International, LLC DC.7
Regulation:	21CFR878.4810
Category of Device:	Prescription Device
Laser Medium:	Diode Laser (GaAlAs)
Wavelength:	980 nm
Power to Tissue:	DC 7: Up to 7 Watts
Laser Class	Class IV
Operating Modes:	Continuous, Pulsed
Pulse Width:	50us – 30s Up to 100 Hertz
Beam Delivery:	Fibers, handpieces and tips
Aiming Beam:	650 nm @ 1.0 mW Max adjustable
Contacting Material	Stainless steel, polypropylene and quartz
Contacting Components	Hanpieces, tips and fiber
Control System	Microprocessor
Laser Operation:	Footswitch
Electrical Supply:	100-230 VAC, 50-60 Hz
Cooling:	Internal
Weight:	3 Pounds
Accessories:	Fiber, disposable tips, handpieces
Software Validation:	Comply with the FDA Guidance for traditional 510(k)

Electrical Safety:	Comply with IEC60601-1
Electromagnetic Compatibility:	Comply with IEC60601-1-2
Labeling:	Comply with the related standards and refer to Labeling documentation of 510(k) submission

Intended Use:
The DC 7 laser and accessories are indicated for General Surgery, Dermatology & Plastic Surgery, and Podiatry: Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:
Matrixectomy
Excision of neuromas
Excision of periungual and subungual warts
Excision of plantar warts
Excision of Keloids
Excision of cutaneous lesions
Photocoagulation of telangiectasia, venulectasia of the legs and face
Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi

Comparison: The DC 7 has the exact technological characteristics, design, material, components, energy source as the China Daheng Group DenLase 980/7 (K102669) and it is similar to the Biolase Technology Diolase 10S, the safety and effectiveness of the DC 7 (K121327) is based upon a determination of the substantial equivalence as well as the safety and effectiveness of the medical devices.

Company/ Specifications	DC International, LLC DC 7	China Daheng Group Inc Denlase 980/7	Biolase, Inc Diolase 10S
Concurrence: 510(k) Number:	K131839	K102669	K121327
Regulation:	21CFR878.4810	21CFR878.4810	21CFR878.4810
Category of Device:	Prescription Device	Prescription Device	Prescription Device
Laser Medium:	Diode Laser (GaAlAs)	Diode Laser (GaAlAs)	Diode Laser (GaAlAs)
Wavelength:	980 nm	980 nm	940 +/- 15 nm
Power to Tissue:	DC 7: Up to 7 Watts	DenLase 7: Up to 7 Watts	Diolase 10S: Up to 10 Watts
Laser Class	Class IV	Class IV	Class IV
Comparison Analysis:	The maximum power output of proposed device is between that of the two predicates devices, and all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.		
Operating Modes:	Continuous, Pulsed	Continuous, Pulsed	Continuous, Pulsed
Pulse Width:	50us – 30s Up to 100 Hertz	50us – 30s Up to 100 Hertz	
The pulse duration of laser should be shorter than thermal relax time of target tissues so that the thermal diffusion will not act on the surrounding tissues during the heating process of the target tissues, in this way the surrounding tissues can be protected. The comparatively short pulse duration of DC7 will not introduce any problems regarding the safety and effectiveness of the device. In addition, the shorter pulse duration will decrease the injury which the laser beam bring to the normal tissue, at the same time the shorter pulse duration will reduce the smoke caused by treatment, then correspondingly optimize the vision during the treatment also. Considering the pulse duration range of the proposed product include the pulse duration range of the predicated product, the difference will not introduce any problems regarding the safety and effectiveness of the device.			
Beam Delivery:	Fibers, handpieces and tips	Fibers, handpieces and tips	Fibers, handpieces and tips
Aiming Beam:	650 nm @ 1.0 mW Max adjustable	650 nm @ 1.0 mW Max adjustable	650 nm @ 1.0 mW Max adjustable
Contacting Material	Stainless steel, polypropylene and quartz	Stainless steel, polypropylene and quartz	Stainless steel, polypropylene and quartz
Contacting Components	Hanpieces, tips and fiber	Hanpieces, tips and fiber	Hanpieces, tips and fiber

Control System	Microprocessor	Microprocessor	Microprocessor
Laser Operation:	Footswitch	Footswitch	Footswitch
Electrical Supply:	100-230 VAC, 50-60 Hz	100-230 VAC, 50-60 Hz	100-230 VAC, 50-60 Hz
Cooling:	Internal	Internal	Internal
Weight:	3 Pounds	3 Pounds	
Accessories:	Fiber, disposable tips, handpieces	Fiber, disposable tips, handpieces	Fiber, disposable tips, handpieces
Software Validation:	Comply with the FDA Guidance for traditional 510(k)	Comply with the FDA Guidance for traditional 510(k)	Comply with the FDA Guidance for traditional 510(k)
Electrical Safety:	Comply with IEC60601-1	Comply with IEC60601-1	Comply with IEC60601-1
Electromagnetic Compatibility:	Comply with IEC60601-1-2	Comply with IEC60601-1-2	Comply with IEC60601-1-2
Regulation:	21CFR878.4810	21CFR878.4810	21CFR878.4810
Comparison Analysis:	The maximum power output of proposed device is between that of the two predicates devices, and all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.		
Labeling:	Comply with the related standards and refer to Labeling documentation of 510(k) submission	Comply with the related standards and refer to Labeling documentation of 510(k) submission	Comply with the related standards and refer to Labeling documentation of 510(k) submission
Based on comparison above, the DC7 Dental Laser Therapy System shares the similar design features and functional features with the predicate devices.			

Summary: From a design and clinical perspective, the predicate and candidate laser device, are the same technology and have the same intended use. Based upon the fact that the devices are exactly the same or extremely similar, the DC 7 should not raise any concerns regarding its overall safety and/or effectiveness.

Non clinical Performance Data: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 7, 2013

DC International LLC
Mr. David Boegler
Vice President
624 Cypress Green Circle
Wellington, Florida 33414

Re: K131839
Trade/Device Name: DC7
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 27, 2013
Received: October 7, 2013

Dear Mr. Boegler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131839

Device Name: DC 7

Indications For Use:

The DC 7 laser and accessories are indicated for General Surgery, Dermatology & Plastic Surgery, and Podiatry: Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis; incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:

Matrixectomy
Excision of neuromas
Excision of periungual and subungual warts
Excision of plantar warts
Excision of Keloids
Excision of cutaneous lesions
Photocoagulation of telangiectasia, venulectasia of the legs and face
Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K131839_____